

4/2012



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
REGION IX LABORATORY  
1337 S. 46TH STREET  
BLDG. 201  
RICHMOND, CA 94804-4698**

George Kulasingam, Ph.D  
California Department of Public Health  
Environmental Laboratory Accreditation Program Branch  
850 Marina Bay Parkway, Bldg P, 1<sup>st</sup> Floor  
Richmond, CA 94804

Dear Dr. Kulasingam:

On November 22, 2011, Andrew Lincoff and Amy Wagner, EPA Region IX Laboratory Certification Officers, conducted the annual overview of California's Drinking Water Certification Program. The overview included discussions with you and members of the Environmental Laboratory Accreditation Program (ELAP) staff in the Richmond office. Mr. Lincoff and Ms. Wagner also reviewed records for certain chemistry and microbiology laboratories recently audited by ELAP. The program overview is a Safe Drinking Water Act requirement for the State to maintain primacy.

We wish to congratulate your staff for their accomplishments in your Laboratory Certification Program. ELAP meets all federal requirements to maintain a laboratory certification program under the Safe Drinking Water Act. ELAP's involvement in the National Environmental Laboratory Accreditation Program (NELAP) and qualification for the state to serve as a NELAP Accreditation Body is commendable. I am enclosing the overview report on the status of your certification program. We are pleased the ELAP program continues to establish high standards for in-state and out-of-state environmental laboratories applying for drinking water certification.

Sincerely,

A handwritten signature in cursive script, reading "Brenda Bettencourt", is positioned above the typed name.

Brenda Bettencourt  
Laboratory Director

Enclosure



OVERVIEW OF  
STATE OF CALIFORNIA's  
DRINKING WATER LABORATORY CERTIFICATION PROGRAM

December 10, 2011

CONDUCTED BY

Andrew Lincoff and  
Amy Wagner

U.S. EPA REGION IX  
LABORATORY CERTIFICATION OFFICERS  
1337 SOUTH 46<sup>TH</sup> STREET  
RICHMOND, CA 94804

## **INTRODUCTION**

On November 22, 2011, Andrew Lincoff and Amy Wagner conducted an overview of the State of California Department of Public Health's Environmental Laboratory Accreditation Program for drinking water. The purpose of the overview is to ensure that the State's delegated laboratory certification program is in compliance with EPA's standards as part of the Safe Drinking Water Act. The overview was conducted according to the procedure set forth in the Manual for the Certification of Laboratories Analyzing Drinking Water Samples - Fifth Edition (the Manual). The overview consisted of discussions with George Kulasingham, ELAP Manager, Jane Jensen, Fred Choske and Shinae Park, and reviews of certification files pertaining to laboratories licensed in 2010-2011.

## **PROGRAM OVERVIEW**

### **Organization/Program Scope and Responsibilities**

There are currently 262 drinking water laboratories licensed by CA ELAP for chemistry, 303 for microbiology, and 21 for radiochemistry. Of these 545 are in-state and 64 are out-of-state. Laboratories are audited once every two years. The drinking water labs are part of the total of 780 environmental labs licensed by CA ELAP.

### **Certification Process**

CA ELAP bases its primary drinking water laboratory certification program on EPA's Manual for the Certification of Laboratories Analyzing Drinking Water Samples – Fifth Edition. Laboratories are licensed by method and analyte. Laboratories may be downgraded based upon criteria in Chapter III of the Manual which includes failure to use mandated methods, unacceptable results on Proficiency Testing (PT) samples, failure to notify the State of changes in address or key personnel, and deficiencies found during on-site evaluations.

CA ELAP is also a TNI accrediting body. Of the 117 drinking water labs certified in 2011, 38 were certified under CA ELAP's primary drinking water certification program, and 78 were certified under NELAP. These labs are audited under the current TNI standard which EPA accepts as equivalent to a primary drinking water certification. TNI labs are also audited on a two-year cycle.



## **FINDINGS**

### **Staffing and Resources**

CA ELAP is a fee-based program and reports generally sufficient resources to handle the current workload. However, none of the auditing staff is a microbiologist, despite the fact that over half of the certified labs are microbiology labs. Hiring a trained microbiologist would be useful to the program. Travel resources also continue to affect the program. Five staff members are currently in need of training, but the ability to attend out-of-state training, such as EPA's Laboratory Certification Officers training course and participation in NELAP, is uncertain. The program would need additional resources to conduct unannounced revisits within 6 months of labs found to have deficiencies.

### **Total Coliform Invalidation**

CA ELAP may be asked to perform technical evaluations or investigations of microbiology laboratories reporting positive coliform results from Public Water Supply Systems. The issue of reasons for invalidation of total coliform drinking water samples was discussed. A total coliform positive result produced by a certified lab, using an approved method, and meeting all method and Quality Control parameters, is valid for compliance purposes. Other information, including previous negative sampling results, negative results upon resampling, or negative results from other laboratories may not be used to invalidate positive results from certified drinking water laboratories.

### **Record Review**

The evaluation included a review of a selection of CA ELAP's recent certification records of public and private drinking water laboratories. The following files were audited:

| <u>Laboratory</u>           | <u>Certification Date</u> |
|-----------------------------|---------------------------|
| Aqualab                     | 3/18/11                   |
| City of Benicia             | 8/16/11                   |
| City of Fort Bragg          | 6/20/11                   |
| City of Santa Cruz          | 6/7/10                    |
| E&J Gallo                   | 6/26/10                   |
| Los Angeles Water and Power | 5/5/11                    |
| Marin County Public Health  | 7/1/11                    |
| Qualtest                    | 6/24/11                   |

San Diego County  
Zalco

7/31/11  
8/1/11

The review of labs certified in the past year showed that audits are thorough and reports are completed within 30 days of on-site visits and often much sooner. Corrective actions and documentation are required for deficiencies before final certification is issued. Documentation of acceptable performance on current PT tests was available for all labs reviewed. ELAP meets all federal requirements to maintain a laboratory certification program under the Safe Drinking Water Act.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
REGION IX  
75 Hawthorne Street  
San Francisco, CA 94105

APR 11 2011

William Draper, Ph.D, Chief  
California Dept. of Public Health  
Division of Drinking Water and Environmental Management  
Drinking Water and Radiation Laboratory  
850 Marina Bay Parkway  
Richmond, Ca 90804-6403

Dear Dr. Draper:

On November 22, 2010, Amy Wagner, Laboratory Certification Officer, conducted an evaluation of the California Department of Public Health Drinking Water and Radiation Laboratory in Los Angeles for the purpose of renewing the laboratory's certification to analyze drinking water samples for microbiology under the U.S. Environmental Protection Agency's Safe Drinking Water Program. Ms. Wagner's evaluation report is enclosed.

It is with pleasure that I hereby grant the California Department of Public Health Drinking Water and Radiation Laboratory in Los Angeles full certification for the microbiological analysis of drinking water using Multiple Tube Fermentation, Colilert, and Heterotrophic Plate Count.

Full certification for these methods will remain in effect until December 1, 2013, provided that the laboratory satisfactorily analyzes annual Performance Testing samples and notifies EPA Region 9 of any significant change in personnel, equipment, or laboratory location within 30 days of such change.

If you have any questions concerning this matter, please call Ms. Wagner at (510) 412-2329. I appreciate the courtesy and cooperation extended to Ms. Wagner during her visit to your laboratory.

Sincerely,

A handwritten signature in black ink, appearing to read "Thomas McCullough".

Thomas McCullough  
Assistant Regional Administrator  
For Management and Technical Services Division

Enclosure

Cc: Angela Anand, CDPH DWRL South  
Dr. Donald Wijekoon, CDPH DWRL North







UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
REGION IX  
75 Hawthorne Street  
San Francisco, CA 94105

MAR 16 2011

Michael Janda, Ph.D., Chief  
California Department of Public Health  
Microbial Diseases Laboratory Branch  
850 Marina Way  
Richmond, CA 94804

Dear Dr. Janda:

On March 8, 2011, Andrew Lincoff, Laboratory Certification Officer, conducted an evaluation of the California Department of Public Health Microbial Diseases Laboratory in Richmond for the purpose of renewing certification of the laboratory for analyzing drinking water samples under the U.S. Environmental Protection Agency's Safe Drinking Water Program. Mr. Lincoff's evaluation report is enclosed.

It is with pleasure that I hereby grant the California Department of Public Health Microbial Diseases Laboratory full certification for the microbiological analysis of drinking water using the Membrane Filtration, Multiple Tube Fermentation, Colilert, Colisure, and Heterotrophic Plate Count. Full certification for these methods will remain in effect until March 1, 2014, provided that the laboratory satisfactorily analyzes annual Proficiency Testing samples and notifies EPA Region 9 of any significant changes in personnel, equipment or laboratory location within 30 days of such change.

If you have any questions concerning this matter, please call Mr. Lincoff at (510) 412-2330. I appreciate the courtesy extended to Mr. Lincoff by Dr. Rita Brenden, Mr. Gregory Inami, Ms. Donna Csuti, and Ms. Joselita Tablante during his visit to your laboratory.

Sincerely,

A handwritten signature in black ink, appearing to read "Thomas McCullough".

Thomas McCullough  
Assistant Regional Administrator  
For Management and Technical Services

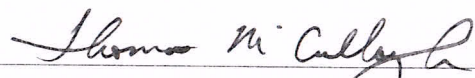
Enclosure



# U S Environmental Protection Agency Region 9

Pursuant to the Safe Drinking Water Act, the  
*CALIFORNIA DEPARTMENT OF PUBLIC HEALTH*  
*MICROBIAL DISEASES LABORATORY*

is hereby Certified for the Microbiological Analysis of Drinking Water  
through March 1, 2014.



Thomas McCullough, Assistant Regional Administrator,  
Management and Technical Services

March 16, 2011

Date



CA0012





On-site Evaluation Report  
of the  
California Department of Public Health  
Richmond Microbial Diseases Laboratory  
For Drinking Water Microbiology

By

Andrew Lincoff  
Laboratory Certification Officer  
U.S. Environmental Protection Agency  
Region 9  
1337 South 46th Street, Bldg. 201  
Richmond, California 94804

Signed:  Date: 3/10/11



## Introduction

On March 8, 2011, Andrew Lincoff, Laboratory Certification Officer (LCO), conducted an onsite evaluation of the of the California Department of Public Health (CDPH) Microbial Diseases Laboratory in Richmond, for the purpose of recertification of the laboratory for analyzing drinking water samples under the U.S. Environmental Protection Agency's Safe Drinking Water Program. Criteria for certification are set forth in the Manual for the Certification of Laboratories Analyzing Drinking Water, Fifth Edition.

The CDPH staff present during the audit were Section Chief, Dr. Rita Brenden, Section Supervisor, Gregory Inami and Public Health Microbiologists Donna Csuti, and Joselita Tablante. The staff are extremely well-qualified and experienced.

The laboratory serves as the Principal State Lab and analyzes a small number of microbiological water samples collected by State and local agencies. Certification was requested for Membrane Filtration, Multiple Tube Fermentation, Colilert, Colisure and Heterotrophic Plate Count.

## Laboratory Facilities

The CDPH Microbial Diseases Laboratory is state of the art. Facilities for drinking water analyses are clean, well organized, and well-equipped. Wastes generated by the laboratory are sterilized onsite in autoclaves.

## Performance Evaluation

The CDPH Laboratory has consistently passed annual microbiology Performance Testing studies provided by NIST-accredited third parties under the National Voluntary Laboratory Accreditation Program.

## Record Keeping and Quality Assurance

The CDPH Quality Assurance Plan is complete and well written. The CDPH Laboratory records are neat and well organized.

## Deviations

The following minor deviations were noted during the audit:





Incubator Thermometer: One 35 °C incubator thermometer had an erroneous calibration factor. However, no instances were observed where this error would have caused the incubator to be out of the required range.

Colilert Bottle Volume Check: The method used to check Colilert bottle volumes has not been consistent. The lab's SOP, which calls for filling the bottle to the 100 mL line and checking the volume gravimetrically, should be followed.

Colilert Incubation Time: The lab's Colilert bench sheet states that 1 hour should be added to the incubation time for samples at room temperature and 2 hours for chilled samples. This is incorrect and should be removed from the benchsheet. The Colilert method development included the time required for samples to reach temperature in the total incubation time. No instances were observed where the Colilert incubation time exceeded the allowable range. It should be noted that Colilert-18 P/A samples must be pre-warmed.

#### Comments and Recommendations

Incubator Calibration: The 35 °C incubators are adjusted to temperature by changing the set point rather than recalibrating the digital temperature controller. The set point should remain at 35.0. When the actual temperature is observed to have drifted consistently above or below the set point, the instrument should be brought back into calibration through the calibration feature rather than by changing the set point.

Autoclave Records: The media prep record sheets produced by LCS list approximate beginning and ending autoclave times which add up to a total of 45 minutes for 15 minute media sterilization cycles. The actual start and end times are printed on the autoclave tape records and should be entered on the record sheets so that media end users will know whether the cycle was actually completed within 45 minutes. It was observed that one recent 15 minute sterilization run on LCS autoclave 3 took a total of 48 minutes, although this was not used for drinking water.

#### Certification Status

I recommend the CDPH Microbial Diseases Laboratory in Richmond be granted Full Certification for microbiological analyses of drinking water to determine compliance with requirements of the Safe Drinking Water Act and the National Primary Drinking Water Regulations using Membrane Filtration, Multiple Tube Fermentation, Colilert, Colisure, Presence/Absence Broth and Heterotrophic Plate Count until March 1, 2014, provided the laboratory satisfactorily analyzes annual Performance Testing samples and notifies Region 9 of any significant changes in personnel, equipment, or laboratory location within 30 days of such change.

